cc: Rodnon/ASM

AC4-29995-00 P

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 2 2001

Re: Sonata
Docket No.: 00E-1234

The Honorable Q. Todd Dickinson
Director of U.S. Patent and Trademark Office
Commissioner for Patents
Box Pat. Ext.
Washington, D.C. 20231

Dear Director Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 4,626,538, filed by American Cyanamid Company, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Sonata, the human drug product claimed by the patent.

The total length of the regulatory review period for Sonata is 3,027 days. Of this time, 2,435 days occurred during the testing phase and 592 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: May 2, 1991.

   The applicant claims May 16, 1991, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 2, 1991, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: December 30, 1997.

   The applicant claims January 13, 1998, as the date the new drug application (NDA) for Sonata (NDA 20-859) was initially submitted. However, FDA records indicate that NDA 20-859 was submitted on December 30, 1997.

3. The date the application was approved: August 13, 1999.

   FDA has verified the applicant's claim that NDA 20-859 was approved on August 13, 1999.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Arnold S. Milowsky
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